K052435

NOV - 3 2005

Attachment 32: 510(k) Summary for the PneumRx Family of Biopsy Needles and Kits

I. General Information

Submitter:	PneumRx, Inc. 530 Logue Avenue Mountain View, CA 94043
Contact Person:	Anne C. Worden VP, Regulatory & Clinical Affairs
Summary Preparation Date:	October 24, 2005

II. Names

Device Names:	PneumRx Family of Biopsy Needles and Kits
Primary Classification Names:	Biopsy Needle and Needle Set

III. Predicate Devices

- Cook® Sidearm Core Tissue Biopsy Device/Set (K041544)
- Biopsy Sciences, LLC. Maxi-Cell Biopsy Needles (K021847)
- Boston Scientific Corp. Interject Injection Therapy Needle (K012864)
- ISPG, Inc. Chiba Needle (K012358)
- INRAD, Inc. AccuCore Core Biopsy Needle (K981166)
- INRAD, Inc. AccuCore Single Action Core Biopsy Device (K000612)
- INRAD, Inc. Co-axial Introducer Needle (K981721)
- Ethicon Endo-Surgery, Inc. Mammotome Biopsy System (K992813)
- Medical Device Technologies, Inc. Tru-Core™ I Reusable Biopsy Instrument (K990839)
- Medical Tech. Introducer Needle for Biopsy Needles (K981889)
- United States Endoscopy Group, Inc. Coaxial Needle (K971842)
- Parallax Medical Clearview Plus Bone and Vertebral Body Biopsy Needles (K022169)
- Stryker Bone and Vertebral Body Biopsy Kit and Stryker Capture Bone and Vertebral Body Biopsy Kit (K032943)
- MD Technologies InterV Brand SnareLok Bone Marrow Biopsy Needle (K043523)
- Orthovita, Inc. Imbibe Bone Marrow Aspiration Needle (K050795)
- Medical Device Technologies, Inc. Chiba, Spinal, Automatic Cutting, General Purpose Introducer, Techna-Cut Biopsy, Super-Core Biopsy, Breast Localization and Simon Breast Localization Needles (K980211)
- MD Manan™ Soft Tissue Biopsy Needles (K980122)
- Daum Corp. Aspiration-Biopsy Needle (K974575)
- Promex/ US Biopsy Prostate Seeding Needle (K973184)
- Klein-Baker Med. Neo-Care Lumbar Puncture Kit (K970997)

- Allegiance Healthcare Clear Hub Spinal Needle (K982269)
- SIMS Spinal Anesthesia Needle (K983858)
- Ferguson Medical SmartGuide (K963894)
- US Biopsy Automated Core Biopsy Device (K994272 and K011270)
- INRAD, Inc. Aspiration Biopsy Needle (K number unknown)
- Cook Chiba Aspiration Biopsy Needles (K851957)
- MD Manan™ Co-Axial Introducer Needles (K980004)
- Manan™ MD Super-Core Biopsy Needle (K974814)
- MD Manan™ Techna-Cut Biopsy Needle (K974766)

IV. Product Description

The PneumRx Family of Biopsy Needles and Kits are comprised of the following main components:

- Standard and steerable biopsy needles in a range of sizes;
- Standard straight and steering stylets compatible with a range of steerable and standard biopsy needles;
- Remote Control Steering Handle accessory;
- Procedure accessories including drapes, gauze sponges, syringes, scalpels, depth markers, and prep tray.

V. Indications for Use

The PneumRx Family of Biopsy Needles and Kits is intended for use in obtaining bone, vertebral body, and bone marrow biopsy specimens, and single and multiple tissue biopsy specimens of tissues or lesions, partial or complete removal of imaged abnormalities, in soft tissues, for applying radionuclide sources into the body, and for aspirating, draining, or injecting various fluids or contents (e.g., sclerosing agents, vasoconstrictors, anesthetics, ethanol, saline, heparin, and other historically used, approved, and/or generally accepted medical fluids in accordance with the judgment and training of the medical practitioner).

The PneumRx Family of Biopsy Needles and Kits is indicated for use in obtaining bone, vertebral body, and/or bone marrow biopsy using coring, cutting or aspiration, as well as providing and maintaining surgical site access with coaxial biopsy needle kits.

They are also indicated for use in percutaneous, open surgical, fine needle, tissue core, coaxial, and aspiration biopsy/ tissue sampling of soft tissues for:

- Microscopic, histologic, diagnostic, evaluation
- Fluoroscopic, ultrasound (US), computed tomography (CT)/x-ray, mammographic imaging, MRI (magnetic resonance imaging) and/or direct visualization
- Guiding biopsy needles to the target lesion
- Avoiding punctures in non-penetrable anatomic obstacles (e.g., bone, spine) or vital structures (e.g., blood vessels, nerves)
- Obtaining multiple biopsy, core biopsy, and aspiration biopsy tissue samples with partial or complete removal of the imaged abnormality

- Aspirating, draining, or injecting various fluids or contents in soft tissues, including introduction of sclerosing agents or vasoconstrictors to control actual or potential bleeding
- Pericardiocentesis, transhepatic cholorangiography, and other applications requiring injection or aspiration of fluids
- Lumbar puncture, spinal fluid sampling, local anesthetic injection to provide regional nerve block/anesthesia, and amniocentesis
- Manual application of a radionuclide source into or on the body for radiation therapy
- Including, but not limited to, the following anatomical locations and lesions:
  - Pleural cavity
  - Lung
  - Lymph nodes
  - Thyroid
  - Adrenals
  - Soft tissue organs of the abdomen and thorax
  - Abdominal cavity/ abdominal soft tissue masses
  - Kidney
  - Liver
  - Spleen
  - Pancreas
  - Prostate
  - Tumors
  - Cysts
  - Fluid spaces
  - Soft tissue lesions or tissue spaces
  - Breast:
    - The PneumRx Family of Biopsy Needles and Kits is indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. It is designed to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality;
    - The extent of a histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality (e.g., malignancy). When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

VI. Rationale for Substantial Equivalence

The PneumRx Family of Biopsy Needles and Kits shares the same or similar indications for use, device operation, overall technical and functional capabilities, and therefore is substantially equivalent for use in obtaining single and multiple tissue biopsy specimens of tissues or lesions for microscopic, histologic, diagnostic, evaluation, for partial or complete removal of imaged abnormalities, in soft tissues, for applying radionuclide sources into the body, and for aspirating, draining, or injecting various fluids or contents to the predicate devices.

In addition, comparative performance test data demonstrated adequate device performance.

VII. Safety and Effectiveness Information

The review of the indications for use and technical characteristics provided demonstrates that the PneumRx Family of Biopsy Needles and Kits is substantially equivalent to the predicate devices.

VIII. Conclusion

The PneumRx Family of Biopsy Needles and Kits was found to be substantially equivalent to the predicate devices.

The PneumRx Family of Biopsy Needles and Kits shares identical indications for use, similar design features, and functional features with, and thus is substantially equivalent to, the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 3 2005

Anne C. Worden
Vice President, Regulatory & Clinical Affairs
PneumRx, Inc.
530 Logue Avenue
Mountain View, California 94043

Re: K052435
Trade/Device Name: PneumRx Family of Biopsy Needles and Kits
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: KNW, FCG, GAA, GDM, DWO
Dated: September 2, 2005
Received: September 6, 2005

Dear Ms. Worden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Bochner
for

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): **K052435**

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Prescription Use ✓ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Brelin

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052435

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bueltmann

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052435